PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**12 JULY 2005 (12.07.2005)**
Applicant's or agent's file reference PCA50318/HMY -S3	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2005/001021	**08 APRIL 2005 (08.04.2005)**	10 APRIL 2004 (10.04.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 47/00, A61P 9/10

Applicant

HANMI PHARM. CO., LTD. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	11 JULY 2005 (11.07.2005)	LEE, Mi Jeong Telephone No.82-42-481-5601

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/001021

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material
   - ☐ a sequence listing
   - ☐ table(s) related to the sequence listing

   b. format of material
   - ☐ on paper
   - ☐ in electronic form

   c. time of filing/furnishing
   - ☐ contained in the international application as filed.
   - ☐ filed together with the international application in electronic form.
   - ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/001021

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 17	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 17	YES
	Claims		NO

2. Citations and explanations :

The following documents are referred to in this report:

D1: US 2002/0044962 A1 (18 Apr. 2002)
D2: US 5916595 A (29 Jun. 1999)

1. Novelty

Claims 1-17 of the present invention relate to a sustained release formulation for oral administration of an HMG-CoA reductase inhibitor comprising a solid dispersant including the HMG-CoA reductase inhibitor(Simvastatin, Lovastatin, etc.), a solubilizing agent(d-alpha-tocopheryl polyethylene glycol 1000 succinate, etc.), and a stabilizing agent(butylated hydroxytoluene, etc.); a sustained release composite carrier(sodium alginate, etc.); and a gel hydration accelerator(propylene glycol ester alginate, hydroxypropyl methyl cellulose, etc.), and a preparation method thereof.

D1 discloses a controlled release encapsulated product including HMG-CoA reductase inhibitor, at least one erodible polymer(hydroxyethyl cellulose, propylene glycol alginate, sodium alginate, etc.) and at least one lubricating material.
D2 discloses a controlled release formulation of a HMG-CoA reductase inhibitor which is based on a combination of (a) a compressed tablet core which contains an alkyl ester of a hydroxy substituted naphthalene derivative, water swellable polymer and an osmotic agent; and (b) an outer coating layer which completely covers the osmotic core and comprises a pH sensitive coating agent and a water insoluble polymer.

Neither of D1 and D2 discloses the said sustained release formulation of a HMG-CoA reductase inhibitor and a preparation method thereof in the present invention.
Therefore, claims 1-17 of the present invention are considered to be novel over D1 and D2 [Article 33(2) PCT].

2. Inventive Step

There is no implication or suggestion to lead those who skilled in the art to expect that
(Continued on the Supplemental Sheet.)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of :

Box V.

a solubilizing agent, a stabilizing agent, a sustained release composite carrier, and a gel hydration accelerator can be combined together to make a sustained release formulation of a HMG-CoA reductase inhibitor, in D1 and D2.

Therefore, the inventive step of claims 1-17 can be acknowledged over D1 and D2 [Article 33(3) PCT].

3. Industrial Applicability

The subject-matter of claims 1-17 appears to be industrially applicable [Article 33(4) PCT].